

NOV 13 2000

Premarket Notification 510(k)

Allon 2001 Modification

Section 2 - Certification and Summaries

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**POB 26, Or Akiva Industrial Park**  
**Or Akiva, Israel 30600**  
**Tel - [972] 6-6266122**  
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## 2.1 Summary of Safety and Effectiveness

### Non-Confidential Summary of Safety and Effectiveness

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POB 26, Or Akiva Industrial Park  
Or Akiva, Israel 30600

Tel - 011-972-6-6266122  
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**Official Contact:** Shlomi Deler, QA Manager

**Proprietary or Trade Name:** Allon 2001 System - modified

**Common/Usual Name:** Thermal Regulating System

**Classification Name:** Thermal Regulating System

**Device:** Allon 2001 System

**Predicate Devices:** M.T.R.E. - Allon 2001 - K001546  
M.T.R.E. - Allon 2000 - K992386  
Cincinnati Subzero - Blanketrol II - preamendment.

### Device Description:

The *Allon 2001* system consists of the following elements:

- Temperature controlled garment
- Body sensors
- Connecting flexible water pipes
- Heating/Cooling Unit

The system operates by circulating water by a pump in a closed loop between a disposable garment worn by the patient. The water circulates through the heater / cooling unit. Temperature (body) sensors are placed on the patient and in the rectum or nasopharynx or esophageal to measure core temperature. The operator selects the desired patient core temperature and the unit operates in an automatic mode. Patient temperature is controlled and maintained at any set point between

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30-40°C using a feedback loop and sensors placed on the patient's body. The heating/cooling unit is based on a solid-state thermo-electric device, which operates as a heat pump. The system is intrinsically safe, due to the characteristics of the thermo-electric device, heating capacity drops off as the Thermo Electro Cooler (TEC) temperature rises. Hence, if for any reason, flow of coolant is interrupted, the TEC will overheat and the power output will fall, thus limiting water temperature rise.

The garment is provided in a variety of shapes and sizes, which are the same as those already cleared under K001546 and K992386.

**Intended Use:**

Indicated Use --	The Allon 2001 is intended to maintain pre-set body temperature as determined by the physician. It can also be utilized to maintain normal body temperature during surgical procedures. This system can be used with adult and pediatric patients.
Patient Population --	This system can be used with adult and pediatric patients.
Environment of Use --	Hospital, invasive and coronary care units, in operating, recovery and emergency rooms, in burn units, and on medical / surgical floors
Contraindications --	The Allon 2001 system should not be in direct contact with open, widespread skin lesions such as burns or dermatitis. The safety and effectiveness of use of the Allon 2001 on patients with multiple trauma has not been established.

**Comparison to Predicate Devices:**

	<i>Allon 2001 – CSZ – Blanketrol K001546 Preamendment</i>	<i>Allon 2001- modified</i>
<b>Equipment Design</b>		
Dimensions	262cm X 53cm X 52cm	The same
Weight	33 Kg (including liquid in the reservoir)	The same
Mobility	Mobile with four wheels.	The same
Power max.	500 W max.	The same
Input power	115/230 V ac with isolation transformer	The same
Water tank	6 liter	The same

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	<i>Allon 2001 – CSZ – Blanketrol K001546 Preamendment</i>	<i>Allon 2001- modified</i>
HCU	Thermo Electro Cooler based on Peltier effect.	The same
Control System		
Water out temp'	15-40.2 °C / CSZ – 4-42 °C	13-40.8 °C
Set Point temp'	32-38.5 °C / CSZ – 30-40 °C	30-40 °C
Flow rate	0.2-1.25Lpm	The same
Pressure rate	0.1-1.3 bar	The same
Safety System		
High primary	40.2 °C / CSZ - 45 °C	40.8 °C
High secondary	41°C / CSZ - 46 °C	The same
High third	-	44 °C
Low primary	15 °C / CSZ - 3 °C	13 °C
Pressure valve	Yes	The same
Safety Alert / Alarms		
Dislodged sensor	Yes	The same
Incorrect Patient temp' setting	Yes	The same
High/Low patient temp' limit.	Yes	The same
Out of normothermia	Yes	The same
High/Low water temp' limit	Yes	The same
Low water	Yes	The same
Low water flow	Yes	The same
Water blocking	Yes	The same
Non – Operating Pump	Yes	The same
Monitoring/indicators		
Water out temp'	Yes	The same
Not enough water in tank	Yes	The same
Water in temp'	Yes	The same
Ambiant temp'	Yes	The same
Patient Surface Temp.	Yes	The same
Patient Auxiliary Temp.	Yes	The same
Patient core Temp.	Yes	The same
Water pressure	Yes	The same
Water flow	Yes	The same
Graphic presentation. Patient temp During treatment	Yes	The same

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	<i>Allon 2001 – CSZ – Blanketrol K001546 Preamendment</i>	<i>Allon 2001- modified</i>
Operating Buttons		
Set Point temp'	Yes	The same
Silence Alarm	Yes	The same

**Differences Between Other Legally Marketed Predicate Devices**

The modified Allon 2001 system is viewed as substantially equivalent to the following predicate device - Allon 2001 system cleared under K001546, the Allon 2000 system cleared under K992386, and Cincinnati Subzero – Blanketrol II - preamendment.

The differences between the Allon 2001 modification and the Allon 2001 and Cincinnati Subzero – Blanketrol II, the predicate devices, are minimal. There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices. They are viewed as substantially equivalent to the predicate devices since they:

1. Have the same intended uses
  - 1.1 Intended to maintain pre-set body temperature as determined by the physician.
  - 1.2 It can also be utilized to maintain normal body temperature during surgical.
2. Have the same environments for use
  - 2.1 Used in hospital, invasive and coronary care units, in operating, recovery and emergency rooms, in burn units, and on medical / surgical floors,
  - 2.2 The device has been designed for stationary and intra-institution transport only.
3. Are similar in design
4. They employ the same technology
5. Are made of identical materials



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 13 2000

MTRE Advanced Technology, Ltd.  
c/o Mr. Paul Dryden  
ProMedic, Inc.  
6329 W. Waterview Ct.  
McCordsville, IN 46055-9501

Re: K003349  
Trade Name: Allon 2001 Modification  
Regulatory Class: II (two)  
Product Code: DWJ  
Dated: October 25, 2000  
Received: October 26, 2000

Dear Mr. Dryden:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

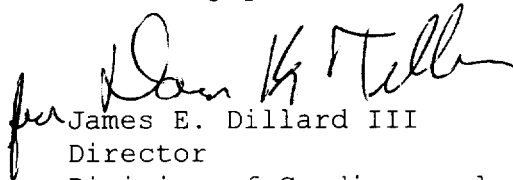
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Paul Dryden

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III", is written over the typed name.

James E. Dillard III  
Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

## 2.3 Indications for Use

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Pursuant to the Notice of February 6, 1996 regarding listing of Indications for Use on a separate sheet, the following is per that request.

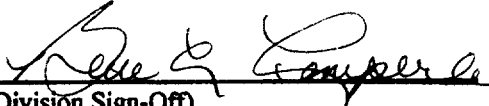
510(k) Number: K003349 (To be assigned)

Device Name: Allon 2001 Modification

Intended Use: The Allon 2001 is intended to maintain pre-set body temperature as determined by the physician. It can also be utilized to maintain normal body temperature during surgical procedures. It is indicated for use in hospital invasive and coronary care units, in operating, recovery and emergency rooms, in burn units, and on medical / surgical floors. This system can be used with adult and pediatric patients.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K003349

Prescription Use \_\_\_\_  
(Per CFR 801.109)

or

Over-the-counter use \_\_\_\_